Maryland Board of Pharmacy
Public Board Meeting

Agenda
July 17, 2019

Name	Title	Present	Absent
Ashby, D.	Commissioner		
Bouyoukas, E	Commissioner		
Evans, K.	Commissioner		
Garmer, G.	Commissioner		
Hardesty, J.	Commissioner/Treasurer		
Laws Jr, A.	Commissioner		
Leikach, N.	Commissioner		
Morgan, K.	Commissioner/President		
Oliver, B	Commissioner		
Rusinko, K.	Commissioner		
Toney, R.	Commissioner/Secretary		
Yankellow, E.	Commissioner		
Bethman, L.	Board Counsel		
Felter, B.	Board Counsel		
Speights-Napata, D.	Executive Director		
Fields, E.	Deputy Director /Operations		
James, D.	Licensing Manager		
Leak, T.	Compliance Director		
Clark, B.	Legislative Liaison		
Chew, C.	Management Associate		

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
I. Executive Committee Report(s)	**A.) K. Morgan, Board President** **B.) R. Toney, Secretary**	*Members of the Board with a conflict of interest relating to any item on the agenda are advised to notify the Board at this time or when the issue is addressed in the agenda.* **1. Call to Order** **2. Sign-in Introduction and of meeting attendees** – *(Please indicate on sign-in sheet if you are requesting CE Units for attendance)* **3. Distribution of Agenda and packet materials** **4. Review and approve May 2019 and June 2019 Public Meeting Minutes**	
II. A. Executive Director Report	**D. Speights-Napata, Executive Director**	**1. Contraception Prescribing and Dispensing Program Report-Deena** **2. Board Vacancy--Deena** **3. Pharmacy School Committee Report--Steve**	
B. Operations	**E. Fields, Deputy Director/ Operations**	**1. Procurement and Budget Updates** **a: June 2019 Financial Statements** **2. Management Information Systems (MIS) Unit Updates** **a: None**	
C. Licensing	**E. Bouyoukas, Commissioner**	**1. Unit Updates** **2. Monthly Statistics**	

License Type	New	Renewed	Reinstated	Total
Distributor	22	177	0	1,354
Pharmacy	26	0	0	2,043

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			Pharmacist	**73**	**453**	**0**	**12,141**
			Vaccination	**31**	**111**	**0**	**4,703**
			Pharmacy Intern - Graduate	**5**	**0**	**0**	**51**
			Pharmacy Intern - Student	**54**	**7**	**0**	**898**
			Pharmacy Technician	**135**	**268**	**5**	**9,885**
			Pharmacy Technician-Student	**0**	**0**	**0**	**34**
			TOTAL	**346**	**1,016**	**5**	**31,193**
D. Compliance	**T. Leak, Compliance Director**	**1. Unit Updates** **2. Monthly Statistics** **Complaints & Investigations:** New Complaints - 26 • Customer Service - 1 • Inspection Issues - 8 • Invalid CPR – 4 • Unlicensed Personnel – 1 • Facility Issues – 3 • Dispensing Errors -5 • Employee Pilferage – 1 • Refusal to Fill – 2					

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		• Unprofessional Conduct -1 Resolved (Including Carryover) – 64 Actions within Goal – 43/64 Final disciplinary actions taken – 27 Summary Actions Taken – 3 Average days to complete – 104 **Inspections:** Total - 155 Annual Inspections - 150 Opening Inspections - 0 Closing Inspections - 3 Relocation/Change of Ownership Inspections - 2 Board Special Investigation Inspections – 0	
E. Legislation & Regulations	**B. Clark, Legislative Liaison**	**Regulations** **Legislation**	
III. Committee Reports **A. Practice Committee**	**Evans, K. Commissioner**	**Shruti R. Kulkarni:** Requesting clarification regarding the pharmacist's ability to administer a controlled medication for opioid use disorder at the direction of a prescribing practitioner in the course of the practitioner's professional practice.	

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		My firm represents a pharmaceutical manufacturer that is developing injectable (non-vaccine) medications that will be administered by a health care provider and, if authorized under state law, pharmacists. Currently, under Maryland Health **Occupations Code Ann.** § **12-101 (g)** the definition of "practice pharmacy" includes the administration of vaccinations and self-administered drugs. **(Md. Health Occupations Code Ann.** § $\mathbf{12-101}$ $(\boldsymbol{g})$. Although the definition does not specifically include the administration of other drugs, it does include "acting within the parameters of a therapy management contract." **(Md. Health Occupations Code Ann. § 12-101 (g)(vii).** Therapy management contracts are agreements between a prescriber and a pharmacist "related to treatment using drug therapy … under defined conditions or limitations for the purpose of improving patient outcomes. **(Md. Health Occupations Code Ann.** § $\mathbf{12-6A-01}$ $(\mathbf{3})$. Protocols established by the physician may authorize the initiation of drug therapy under written, disease-state specific protocols and the modification, continuation, and discontinuation of drug therapy under written, disease-state specific protocols. **vaccines (Md. Code Occupations Code Ann. §12-6A-06)** regulations contain specific provisions related to the administration of vaccine, **COMAR 10.34.32** and self-administered drugs (e.g., insulin), **COMAR 10.34.39.00.** We interpret this definition to mean that a pharmacist may administers medications for substance use disorder, including controlled substances indicated for the treatment of opioid use disorder, at the direction of a prescribing practitioner in the course of the practitioner's professional practice. I respectfully request that you confirm that our interpretation is in the line with that of Maryland's Board of Pharmacy. **Proposed Response:** Thank you for your inquiry. The Board of Pharmacy does not share your interpretation of the law. Under Maryland law, pharmacists are permitted to administer only two types of drug treatment: self-administered drugs (including self-administered injections), and vaccinations that are either 1) listed in the Center for Disease Control and Prevention's Recommended Immunization Schedule or 2) recommended in the Centers for Disease Control and Prevention's Health Information for International Travel. *See*	

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		Md. Code Ann., Health Occ. § 12-509 and § 12-508. The injection you have described, therefore, would exceed a pharmacist's scope of practice, as defined in Md. Code Ann., Health Occ. § 12-101(g), et al., and is therefore prohibited under Md. Code Ann., Health Occ. § 12-6A-06(2) which provides that a drug therapy management protocol "may not authorize acts that exceed the scope of practice of the parties to the therapy management contract." **Woroma Ejiowhor:** I have a question regarding the protocol of reporting losses of controlled substances. COMAR 10.34.05 requires pharmacy permit holders to report thefts or significant losses concerning controlled substances for MD residents or any loss that occurs regardless of whether the controlled substances were intended for MD residents? My company, Envolve Pharmacy Solutions, is a non-resident pharmacy with no physical locations in Maryland. Are we still required to report losses of controlled substances to the board? If we are required to report this information, are we only required to report losses concerning controlled substances for MD residents or any loss that occurs regardless of whether the controlled substances were intended for MD residents? **Proposed Response:** Thank you for your inquiry. In the situation that you have described, the pharmacy in question should comply with the laws of its home state, pursuant to Md. Code Ann., Health Occ. § 12-403(g)(4) and COMAR 10.34.37.04B(12). **Eric Gross:** We have reviewed your state's statutes, rules and regulations, and have several questions with regard to the wholesale distribution of sample prescription skin creams into and within your state. These questions remain separate from the reporting requirements under the PDMA. 1. Can a licensed non-resident wholesale drug distributor ship prescription sample skin creams to a Manufacturer's Authorized Representative (sales representation)?	

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		2. Can a licensed non-resident 3PL (if applicable) ship prescription sample skin cream to a Manufacturer's Authorized Representative (sales representative)? 3. What type of licensure is required by a manufacturer for their Authorized Representative (sales representative) to distribute sample/demonstration product to physicians (e.g., no licensure required for an individual sales rep, manufacture licensure for representative to distribute, etc.?). 4. Is a wholesale drug distributor or 3PL required to verify the licensure (if any) in #3. **Proposed Response:** 1. Yes, a wholesale drug distributor may ship prescription sample skin creams to a manufacturer's authorized representative. 2. The Maryland Board of Pharmacy does not license third-party logistics providers and therefore does not have a position on this matter. 3. This activity does not constitute wholesale distribution. No additional licensure is necessary. 4. Because the activity described in question 3 is not considered wholesale distribution, this question is not applicable. **Jonathan Goldberg:** I am a consumer with issues concerning diabetic medicines Tresiba and Fiasp sold in subcutaneous injection pens of 3 ml each. I don't know why, but at least for Fiasp, the pharmacy is trying to sell me a total of 10 pens (2 boxes of 5 pens) for a 30 day supply and using a sliding scale for the daily dose, as needed. However, the doctor called in a 90 day supply. I witnessed him doing this during my visit, and then I had his nurse confirm when the pharmacy data on file (electronically) disagreed. While Fiasp is a new prescription for me, my Tresiba (a standing prescription) had the same issue (only I did not think fast enough and catch it in time). This is also based on a sliding scale, as needed. What is going on here? Why can't I get 90 day supply at my pharmacy, a	

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		larger supply (as opposed to the 30 day supply) that is SUPPOSED to be saving me money. And, why do I have to fight with the pharmacy every time? Shouldn't they be following doctor's orders? **Proposed Response:** Thank you for your inquiry. The Board understands your frustration; however, because it is likely that the issue you are experiencing is due to an insurance issue, the Board suggests that you reach out to your pharmacist and your insurance provider for further information. **Trina Leak:** I received a question regarding labeling requirements for unit dose medications that are provided to a nurse and then immediately administered to patients per a doctor's order. Does the label need to have an expiration date, or is it sufficient that the unit dose packaging contains the expiration date? **Proposed Response:** Under Code of Maryland Regulations (COMAR) 10.34.03.09, as long as the unit dose packaging has a label on it, the packaging is compliant. **Wendy Rice:** I have looked in the MD 2018 pharmacy law book and cannot find an answer to my question. We provide infusion pharmacy services to patients at an inpatient hospice. The hospice would like us to dispense single dose vials of morphine pursuant to a prescription for hospice stock. They have several patients in need of the morphine now and would like to have some on hand for when their other patients are in need of it. I was under the impression a prescription would need to be faxed to us for each patient as they need the morphine. Please clarify. It would make it easier for the hospice and would enable patients to receive the morphine more quickly if it could be dispensed as stock. **Proposed Response:** A prescription written for "hospice stock" is not permissible for a scheduled substance under federal regulation 21 C.F.R. 1306.05(a), which requires that	

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		prescriptions for controlled substances contain, among other things, "the full name and address of the patient." Your initial determination that a patient-specific prescription for morphine is thus correct. **Darvin Joy:** Our pharmacy has a manufacturer client with a controlled drug for opioid addition. Since the drug would need to be ordered and administered directly by the physician at the point of care, we Wanted to propose a model where our pharmacy would dispense the drug through an automated dispensing machine (placed in the physician's office) with a direct live video link to a pharmacist. Could you provide me some information on how we would go about making a case to the board to change or add new law that would allow this practice? **Proposed Response:** Thank you for your inquiry. The model that you have proposed is not compliant with Maryland Law. Pursuant to Md. Code Ann., Health Occ. § 12-605(a)(3), a remote automated medication system such as the one that you have described may only be located in a health care facility. Md. Code Ann., Health Occ. § 12-605(a)(2) defines a health care facility as "a related institution as defined in § 19-301 of the Health General Article." Because the definition in Health General § 19-301 does not include doctor's offices, it is not permissible to place an automated medication system in a physician's office, as you have described. For information on lobbying to have state laws revised, please contact your local legislator. **Stephen Wienner:** This question is in response to an attempted chargeback from a PBM, because they deem that I filled an invalid prescription as a result of an improperly documented transfer. I will describe the pertinent information and would like the board's opinion as to whether a board inspector or the board would consider this to be an invalid prescription. I have to respond to the audit by May 17, 2109. I know this is a tight window and may not necessarily jive with the committee's that might need to discuss this issue, but any help in getting an expedited opinion would be greatly appreciated. Additionally, the issue that I am about to present happens in many	

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		pharmacies throughout the country, and if the scenario that I describe does indeed create invalid prescriptions, the Maryland Board of Pharmacy should engage in an education campaign, so other pharmacies are not put in the same precarious financial situation because of predatory PBM audits, as I have been. I have two pharmacies with similar names, Mt. Vernon Pharmacy (Referred to as Pharmacy A) and Mt. Vernon Pharmacy at Fallsway (Referred to as Pharmacy B). The physician mistakenly had Pharmacy B listed as the patient's pharmacy of choice in the physician's EMR system, when in actuality the patient used Pharmacy A. When the electronic prescription was transmitted to Pharmacy B, they saw that the patient had never filled a prescription at Pharmacy B. Pharmacy B realized that the physician's office was in close proximity to Pharmacy A, called Pharmacy A, and confirmed that indeed the patient had a long and constant history with Pharmacy A. The pharmacists at both stores realized that the prescription was transmitted to the wrong pharmacy. Pharmacy B printed out the EMR prescription and faxed the information to Pharmacy A. The patient, as both pharmacists suspected, arrived at Pharmacy A, and picked up the prescription as prescribed by his physician. The patient was never inconvenienced or delayed. Additionally, the patient's relationship with Pharmacy A was so good as a result of him being a MedSync patient with Pharmacy A. Because he was a MedSync patient, he actually spoke with a pharmacist or technician of Pharmacy A, each and every month to recheck and confirm his medication regimen. Upon auditing this prescription, an auditing company, SCIO, is trying to capture back the payment for the prescription because they are saying that Pharmacy A filled an invalid transfer (None of the typical info. related to a transferred prescription was written on the hard copy). There are two reasons that I would argue that this was a validly filled prescription, where two pharmacies corrected a keypunch error in the physician's EMR system. One: The practice of pharmacy is a profession, not a trade. Though there are	

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		laws to protect patients and the public, a pharmacist using common sense and professional judgment should be permitted to make and clarify grey area issues for the benefit of the patient when no harm will result, when the pharmacist is clearly following the intent of the prescriber, and to generally benefit the patient. Two: For a prescription to truly be a valid transfer, the prescription needs to be transferred from an original pharmacy that the patient originally chose. A prescriber is not allowed to take away a patient's freedom of choice with respect to pharmacy providers (intentionally or unintentionally). In the scenario I described that happened to my patient, as well as other patients across this country, the patient never chose or desired to have his prescriptions sent to pharmacy B. The two pharmacies were merely correcting what is normally an innocuous error that occurs in the world of EMR prescriptions. These are the pertinent circumstances and issues that I believe on their own defend this fill by Pharmacy A as a valid prescription. Additionally, the physician has wrote a letter attesting that it was his desire to send the prescriptions to the patients' pharmacy of choice, and not Pharmacy B. Also, the prescription was for a HIV prescription, and any delay in getting these types of prescriptions to patients could be catastrophic in the form of HIV drug resistance. If the board, indeed determines this to be an invalidly filled prescription, I believe the "profession of pharmacy" will be reduced to the "trade of pharmacy." PBM's should not be allowed to weaponize pharmacy practice laws to capture back pharmacy funds in a predatory manner. **Proposed Response:** The Board of Pharmacy does not consider the transaction that you have described to meet the definition of a transfer under COMAR 10.34.04. The Board therefore considers the transaction to be a valid prescription that was ultimately filled by pharmacy B in compliance with state regulations. **Maryna Blom:**	

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		Hello, We are applying for a pharmacy license and in order to ensure we are in compliance I have a few questions please. 1) We are a pharmacy serving patients with diabetes (mainly legend and non-legend devices, insulin pumps and related supplies) and our prescription order forms require extensive clinical data such as A1C values etc. After the patient indicates that he would like to fill his prescription order with us, we send an order form with our fax number, name and address and all the pertinent clinical information required to the prescriber to facilitate clear communication. This form ultimately becomes our prescription hard copy, and thus bears the name, fax and phone number of the pharmacy. This is still in compliance with Maryland regulations, correct? 2) Are pharmacy support staff allowed to give patients pricing information upon patient request or does that have to be done by a pharmacist only? 3) Are prescriptions for Maryland patients allowed to be filled and signed/ checked off by our California pharmacists or do all Maryland prescriptions have to be filled by me (the Maryland Pharmacist)? I have the same question regarding counselling on prescriptions for patients in Maryland: May another staff pharmacist counsel Maryland patients on their prescription or is it required to be me? 4) In the scope of our practice we don't ever use a class A balance. Can that requirement be waived please? **Proposed Response:** 1. No, this is not in compliance with Maryland law. Md. Code Ann., Health Occ. § 12-313(b)(11) provides that it is a violation for a pharmacist or pharmacy to provide or cause to be provided to any authorized prescriber "prescription forms that bear the name, address, or other means of identification of a pharmacist or pharmacy." The law does not make an exception for electronic formats or for situations where the patient contacted the pharmacy directly. 2. Yes, it is permissible for support staff to give pricing information to patients upon request. 3. Both of these practices are permissible; however, the Maryland pharmacist remains responsible for all care provided to Maryland patients under COMAR 10.34.37.04B(2).	

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		4. Under COMAR 10.34.07.01-1A, a Class A prescription balance is only required if it is applicable to the pharmacy.	
B. Licensing Committee	**D. Ashby, Chair**	**1. Review of Pharmacist Applications:** **a. #117982- The applicant states that her current MDBOP application will expire on 07/11/2019, but she wanted to be proactive in making sure all of the Board's paperwork was filed and she is now preparing to take MPJE?NAPLEX exams. She has submitted a new application on 05/22/2019, in anticipation to schedule the NAPLEX exam. She has made many attempts at the MPJE and she was successful with a passing score in April 03/2018. Her first request is she would like an extension of her passing MPJE expired exam score report. She is also requesting that her new MDBOP application, that was submitted in May 2019 be processed; so there is no delay in her scores being received and test being completed.** ***Committee' s Recommendation: Approve 6 mos.*** **b. #116746- The applicant is requesting that she be granted exam eligibility expiration date extensions. Her MPJE and NAPLEX ATTs are due to expire on 8/23/2019. The Board granted the applicant's MDBOP application a six-month extension, which will expire in the month of November 2019.** ***Committee' s Recommendation: Approve*** **a. #23509- I currently live in Connecticut and have been practicing. Although I have not needed to use my Maryland license after obtaining it in 2016 during residency training in Maryland, I have kept it active in case I move back to the Maryland area in**	

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		the future. However, I regrettably did not meet the renewal deadline of 5/31/19 as I failed to remember that Maryland sends renewal notices via mail (vs. Connecticut notifications via email), and unfortunately did not locate this letter at my home. **I apologize for this delay. Now that I am 11 days past the deadline, I am sending this email to inquire if there is any possibility that the additional reinstatement fee can be waved. I appreciate your consideration and understand if this is not possible.** ***Committee' s Recommendation: Deny*** **2. Review of Pharmacy Intern Applications: NONE** **3. Review of Pharmacy Technician Applications: NONE** **4. Review of Distributor Applications: NONE** **5. Review of Pharmacy Applications: NONE** **6. Review of Pharmacy Technicians Training Programs:** **a. Orchard Pharmacy-** ***Committee' s Recommendation: Approve*** **b. Your Community Pharmacy Technician Training Program-** ***Committee' s Recommendation: Approve***	

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		c. PassAssured, LLC (LR)- ***Committee' s Recommendation: Approve*** ***d.* D L- I am working on an update for the YOUR Community Pharmacy Technician Training program and had a couple of questions. Considering more independent pharmacies are asking for permission to use our program than in the past, I wanted to change the name of the program to the PEER Pharmacy Technician Training Program. PEER is short for Pharmacy Ethics, Education & Resources, a non-profit that I founded in 2015. This way the program is independent of our pharmacy name. If I include the name change with the minor content and test question changes, would I need to submit this as an entirely new program or can it still be considered just an update? Would I need to submit another application fee (I did not have to submit the fee for our last update)?** ***Committee' s Recommendation: Approve*** **7. New Business:** **a. MTJ- Does not meet CE qualification** ***Committee' s Recommendation: Deny*** ***b.* AR- Does not meet CE qualification** ***Committee' s Recommendation: Deny***	
C. Public Relations Committee	**E. Yankellow, Chair**	**Public Relations Committee Update:**	

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D. Disciplinary	**J. Hardesty, Chair**	**Disciplinary Committee Update**	
E. Emergency Preparedness Task Force	**N. Leikach, Chair**	**Emergency Preparedness Task Force Update**	
IV. Other Business & FYI	**K. Morgan, President**		
V. Adjournment	**K. Morgan, President**	**A. The Public Meeting was adjourned.** **B. K. Morgan convened a Closed Public Session to conduct a medical review committee evaluation of confidential applications.** **C. The Closed Public Session was adjourned. Immediately thereafter, K. Morgan convened an Administrative Session for purposes of discussing confidential disciplinary cases.** **D. With the exception of cases requiring recusals, the Board members present at the Public Meeting continued to participate in the Closed Public Session and the Administrative Session.**	